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10/796,585	03/09/2004	John O'Dea	011566US1	1115

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EXAMINER

EREZO, DARWIN P

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3773

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/796,585	Applicant(s) O'DEA, JOHN	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-30 is/are pending in the application.
- 4a) Of the above claim(s) 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-26 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to the applicant's communication filed on 10/7/09.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 17-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 17 recites the limitation "the characteristic output" in line 10. There is insufficient antecedent basis for this limitation in the claim. Note that the "monitor" limitation only states that a characteristic is monitored. It does not state that an output is provided by the monitor.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 17, 18, 20-22, 24, 25 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,660,170 to Rajan et al. in view of US 5,134,995 to Gruenke et al.

(claim 17) Rajan discloses an apparatus for providing pressure support comprising:

- a gas flow generating system **6**;
- monitoring means **8**; and
- a controller **14**.

Rajan discloses that the controller delivers inspiration pulses having a starting pressure at PEEP (positive end-expiratory pressure) level and an end pressure at PIP (peak inspiratory pressure) level (col. 6, ll. 27-32). The PEEP value is disclosed to have any value larger than or equal to zero, but is normally lower than 20 cmH₂O when determining the opening pressure (col. 6, ll. 32-34). However, the PEEP can also be above this value if it is necessary to open a collapsed lung (col. 6, ll. 37-39). Thus, PEEP is used as the "opening pressure", which is maintained during the expiratory phase of a breathing cycle. The PEEP value would also be an intrinsic component of the breathing cycle.

Rajan is silent with regards to the controller determining an average intrinsic PEEP over a plurality of breathing cycles based on an output of the monitoring means, and for controlling the gas flow generating system such that a pressure of the flow of

gas delivered to the subject during at least a portion of an expiratory phase of a breathing cycle substantially corresponds to the average PEEP.

Instead, Rajan discloses that the controller determines a “gas flow” (not pressure) over a plurality of breathing cycles based on an output of the monitoring means, and controlling the gas flow generating system such that opening pressure, which is a pressure that is delivered during at least a portion of the expiratory phase to keep the lungs open, corresponds to the average gas “flow” (col. 6, ll. 46-52). That is, Rajan uses the gas flow value as it relates to PEEP to determine the opening pressure during inspiration (see Figure 4, which shows the direct correlation between the monitored gas flow and pressure). As stated above, Rajan discloses that opening pressure is directly related to the end expiratory pressure.

However, Gruenke discloses that it is well known in the art to provide a ventilator comprising a controlling means that determines an average gas pressure (instead of gas flow) over a plurality of breathing cycles (col. 12, ll. 45-50), and controlling a gas flow generating system to adjust the delivery of gas based on the calculated average gas pressure (col. 12, ll. 62 – col. 13, ll. 2).

Gruenke shows that a calculated average gas pressure can also be used to control the delivery of gas to a patient, thus making it a well known equivalent to the means taught by Rajan.

Therefore, because the means taught by Rajan and Gruenke were art recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the means of Gruenke for the means

taught by Rajan. Also, it has been held that use of a known technique (such as the teaching of Gruenke) to improve similar devices in the same way, or a simple substitution of one known means for detecting pressure for another will yield predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

(claim 18) As seen in Fig. 2, a portion of the pressure level during the inspiratory phase is higher than the baseline PEEP.

(claims 20 and 22) The monitoring means **8** is proximate the airway of the subject, wherein the monitoring means is connected to the controlling means via a wire (shown in the circuit diagram of Fig. 2). It is also noted that the term “proximate” is a relative term.

(claim 21) Fig. 2 shows a circuit diagram of the device being connected to the patient. Therefore, it would be inherent for the system to have a patient circuit interface for the device to deliver the oxygen to the patient.

(claim 24) Rajan discloses a pressure gauge/transducer **10**.

(claim 25) The device of Rajan is fully capable of being portable.

(claim 30) Rajan, as modified by Gruenke, also discloses the method of providing the device about to deliver a flow of gas to a patient, wherein the PEEP and other respiratory parameters are determined; and wherein the pressure of gas delivered to the patient is controlled based on the average of these parameters (see the updated rejection to claim 17 above).

8. Claims 19 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajan et al. in view of Gruenke et al., as applied in the rejections to claim 17 above, and in further view of US 5,551,419 to Froechlich et al.

Rajan discloses a device gas flow generating system having a regulating unit **2**, which is Servo Ventilator 300, and the controlling means **14** controlling the pressure supplied by the gas flow generating system **6**. Rajan is silent with regards to how the gas flow generating system is controlled by the controlling unit (e.g., by controlling the speed of the blower). However, Froechlich discloses a similar device having a gas flow generating system **12** and a controlling means **17**, wherein gas flow generating system is a blower. Therefore, since both gas flow generating system are well known in the prior art and both perform the function of regulating the amount of gas pressure delivered to a patient, one of ordinary skill in the art would have found it obvious to replace the gas flow generating system of Rajan with the system taught by Froechlich.

9. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rajan et al. in view of Gruenke et al., as applied to the rejections to claim 17 above, and in further view of US 5,868,133 to DeVries et al.

Rajan is silent with regards to the monitoring means being connected to the controlling means via a wireless signal. However, DeVries teaches a medical device in which components are connected via hard wire or wireless (col. 12, lines 41-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the hard wire connection of Rajan with a wireless

connection because using a wireless connection or hard wire connection is a mere design choice that would be available to one of ordinary skill in the art.

Response to Arguments

10. Applicant's arguments filed 10/7/09 have been fully considered but they are not persuasive.

The applicant argued that Rajan fails to monitor the "intrinsic pressure" of a subject's breathing cycle. This is not found persuasive as Rajan monitors both the flow rate and pressure during the subject's breathing cycle. The monitored pressure would include the intrinsic pressure, which is the pressure monitored at the end of expiration.

With regards to Rajan failing to teach monitoring over numerous cycles, it is noted that Rajan does disclose monitoring the flow rate of several inspiration pulses (col. 6, ll. 46-52), which is considered "over numerous cycles". Also, as seen in Fig. 5, the monitored flow rate is disclosed to be directly related to the opening pressure, which is directly related to PEEP. Thus, Rajan's monitoring means indirectly monitors the PEEP value by monitoring the flow rate.

Note that Gruenke reference is merely being provided to show that it is also well known in the art to monitor and average "gas pressure" instead of "flow rate", which would provide the same output to the controller for determining an "opening pressure" or PEEP value.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/
Primary Examiner, Art Unit 3773